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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/408,905	09/29/99	WALSH K	S1237/7011/E

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EXAMINER	
NICKOL,G	
ART UNIT	**PAPER NUMBER**
1642	11

DATE MAILED: 08/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/408,905	Applicant(s) WALSH, KENNETH	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *26 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 1-38 are pending and are under consideration.

Election/Restrictions

Upon review and reconsideration:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a method of treating myocardial infarction by administering an Akt molecule, classified in class 514, subclass 2.

II. Claims 1, 6-7 drawn to a method of treating myocardial infarction by administering an Akt molecule further comprising co-administering an anti-atherosclerotic agent, classified in class 514, subclass 2.

III. Claims 1,8-9, drawn to a method of treating myocardial infarction by administering an Akt molecule further comprising co-administering a growth factor, classified in class 514, subclass 2.

IV. Claims 10-15, drawn to a method for inhibiting apoptotic cell-death of cardiomyocytes, classified in class 435, subclass 4.

V. Claims 16-19 drawn to a method of inhibiting apoptotic cell-death of vascular endothelial cells comprising contact with an Akt molecule, classified in class 435, subclass 4.

VI. Claims 16, 20-21 drawn to a method of inhibiting apoptotic cell-death of vascular endothelial cells comprising contact with an Akt molecule further comprising co-administering a growth factor, classified in class 435, subclass 4.

VII. Claims 22-23, drawn to a method for treating a condition associated with increased apoptotic-cell death of vascular endothelial cells, classified in class 514, subclass 2.

VIII. Claims 24-25, drawn to a method of inhibiting apoptotic cell death of a skeletal myocyte, classified in class 435, subclass 4.

IX. Claims 26-27, drawn to a method of treating a condition associated with increased apoptotic cell death of a skeletal myocyte, classified in class 514, subclass 2.

X. Claims 28-32, drawn to a composition comprising an isolated Akt nucleic acid operably linked to a gene expression sequence classified in class 536, subclass 23.1.

XI. Claims 28,32-33 drawn to a composition comprising an isolated Akt nucleic acid operably linked to a gene expression sequence further comprising an anti-atherosclerotic agent classified in class 536, subclass 23.1; class 530, subclass 350+.

XII. Claims 34-36, drawn to a method of screening for an inhibitory agent that inhibits apoptotic cell-death of cells in vitro classified in class 435, subclass 4.

XIII. Claims 34,37-38 drawn to a method of screening for an inhibitory agent that inhibits apoptotic cell-death of cells in vivo classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX, and XII-XIII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The Inventions of Groups X and XI are separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups I-IX, XII-XIII and X and XI are not at all related because the compositions of Groups X and XI are not used in any of the methods of Groups I-IX, XII-XIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

SPECIES:

Group II (Claim 7) and Group XI (Claim 33) are generic to a plurality of disclosed patentably distinct species comprising the following distinct molecules:

HMG-CoA reductase inhibitor, a diuretic, an antiadrenergic agent, a vasodilator, a calcium channel antagonist, an angotensin-converting enzyme inhibitor, an angiotensin II antagonist, and a clot dissolver.

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group IX (Claim 27) is generic to a plurality of disclosed patentably distinct species comprising the following conditions: muscular dystrophy, spinal muscular atrophy, anabolic steroid-induced muscle injury, skeletal muscle oxidative stress, physical exercise, and unloading-induced skeletal muscle atrophy, all of which differ, at least, in etiology, pathology, and or mechanisms.

Groups X and XI (Claim 28), and Group XII (Claim 36) are generic to a plurality of disclosed patentably distinct species comprising the following distinct cell types:

cardiomyocytes, skeletal muscle cells, and vascular endothelial cells.

The above species represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group XIII (Claim 38) is generic to a plurality of disclosed patentably distinct species comprising the following distinct tissue types:

myocardium, skeletal musculature, and vascular endothelium.

The above species represent separate and distinct tissues with different morphologies and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 26, 2000

SUSAN UNGAR, PH.D
PRIMARY EXAMINER